From the INTERNATIONAL SEARCHING AUTHORITY

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION (FOT Rule 44.1) Date of mailing (day/monit/year) 2 1 MAR 2008 Applicant's or agent's file reference O7184-15 International application No. PCT/US04/11485 FOR FURTHER ACTION See paragraphs 1 and 4 below international application No. PCT/US04/11485 The applicant is hereby notified that the international search report and the written opinion of the International Searching Authori have been established and are transmitted between the PF PPHARAMACBUTICALS 1. When The time limit for filing such amendments is normally two months from the date of transmittal of the international ger amendments and statement under Article 19; The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46): When The time limit for filing such amendments is normally two months from the date of transmittal of the international state report. Where The time limit for filing such amendments is normally two months from the date of transmittal of the international state report. Where The time limit for filing such amendments is normally two months from the date of transmittal of the international state report. Where The time limit for filing such amendments is normally two months from the date of transmittal of the international state (17(2)) to the International Bureau of WIPO, 34 chemin dee Colombettes 1211 Geneva 20, Switzerland, Facsimal No. (41-22) 338.8.2.70. For more detailed instructions, see the notes on the accompanying sheet. 2. The applicant is hereby notified that no international search report will be entitished and that the declaration under Article 17(2)(3) to that effect and the written opinion of the international Bureau topyther with the applicant's request to forward the texts of the the protest declaration under Article 17(2)(3) to the international pure and the protest declaration under Article 17(2) to the internati	To: JENNIFER M. MCCALLUM	PCT
Date of mailing (day/month/year) 2 1 MAR 2008	THE MCCALLUM LAW FIRM, LLC 132 KOLAR CT.	
Cay/month/year* S. I. WIAN ZUUG Applicant's or agent's file reference FOR FURTHER ACTION See paragraphs 1 and 4 below	·	(PCT Rule 44.1)
International application No. PR PHARAMACBUTICALS International filling date (daymonth/year) 12 April 2004 (12.04.2004) Applicant PR PHARAMACBUTICALS I. Applicant is hereby notified that the international search report and the written opinion of the International Searching Authoric have been setablished and are transmitted herewith. Filling of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the solaims of the international application (see Rule 46): Wheat? The time limit for filling such amendments is normally two months from the date of transmittal of the international search report. Where? Directly to the International Bureau of WIPO, 34 chemin dee Colombettes 1211 Geneva 20, Switzerland, Pacsimile No.: (44-22) 338,82.70. For more detailed Instructions, see the notes on the accompanying sheet. The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith. With regard to the protest against payment of (aa) additional fee(s) under Rule 40.2, the applicant is notified that; the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices. no decision has been made yet on the protest; the spilicant will be notified as soon as a decision is made. Reminders Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant my subset to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination event has been or is to be established. T	•	
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Volume II, National Chapters and the WIPO Internet site. Name and mailing address of the ISA/US Mail Stop PCT, Atm: BA/US Commissioner for Patents P.O. Box 1450 Authorized officer Konata M. Georgo		
Mail Stop PCT, Atm: ISA/US Commissioner for Patents P.O. Box 1450 Konsta M. Georgo		
Commissioner for Pstents P.O. Box 1450 Konsta M. George		Authorized officer
	Commissioner for Patenta	Konsta M. Georgo
Facsimile No. (571) 273-3201	Alexandria, Virginia 22313-1450	Telephone No. (571) 272-0600

Form PCT/ISA/220 (Jamuary 2004)

(See notes on accompanying sheet

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 007184-15	FOR FURTHER ACTION		orm PC17ISA/220 · e applicable, itera 5 below.
International application No. PCT/US04/11485	International filing date (day/me 12 April 2004 (12,04.2004)	onth/year)	(Earliest) Priority Date (day/month/year) 10 April 2003 (10.04.2003)
Applicant PR PHARAMACEUTICALS			
This international search report has bee according to Article 18. A copy is bein	n prepared by this International S g transmitted to the International	earching Auth Bureau.	nority and is transmitted to the applicant
This international search report consists It is also accompanie	of a total of <u>A</u> sheets. d by a copy of each prior art doct	iment cited in	this report.
Basis of the Report With recard to the language, the	international search was carried or	at on the basis	o.A
	application in the language in which		
a translation of t	he international application into irmished for the purposes of interna		, which is the language
b. This international search repartment authorized by or notified to	ourt has been established taking into this Authority under Rule 91 Rule	o account the t 43.6 <i>bis(a)</i>	rectification of an obvious mistake
		sclosed in the	international application, see Box No. I.
2. Certain claims were found	unsearchable (See Box No. II)		• •
 Unity of invention is tacking With regard to the title. 	g (See Box No. III)		
4. With regard to the title, the text is approved as subm	Ital be the annihera		
	by this Authority to read as follow		
	A mas warmetrik to seen as fortow	· ·	
			·
•	•		
•	•		
			•
5. With regard to the abstract,			
the text is approved as submi	ited by the applicant.	•	
the text has been established,	according to Rule 38.2(b), by this	Authority as it	spears in Box No. IV. The applicant port, submit comments to this Authority.
6. With regard to the drawings,	ublished with the abstract is Figure	•	,
. as suggested by the s	•		
as selected by this A	wthority, because the applicant fails	ed to suggest a	figure.
	uthority, because this figure better		•
b. none of the figures is to be pu			
rm PCT/ISA/210 (first sheet) (April 2007)			·

INTERNATIONAL SEARCH REPO	ORT	international app	ication ivo.
		PCT/US04/11485	;
A. CLASSIFICATION OF SUBJECT MATTER IPC: A61K 9/14(2006.01),9/50(2006.01)	-		
USPC: 424/489,499 According to International Patent Classification (IPC) or to both r	national classification and	IPC	
			•
B. FIELDS SEARCHED Minimum documentation searched (classification system followed U.S.: 424/489,499	by classification symbol	s)	
Documentation searched other than minimum documentation to the	e extent that such docum	ents are included in	the fields searched
Electronic data base consulted during the international search (nan WEST, USP, EP, JP, Derwent, PGPB	ne of data base and, when	e practicable, searc	n terms used)
C. DOCUMENTS CONSIDERED TO BE RELEVANT			
Category * Citation of document, with indication, where			Relevant to claim No.
A US 6,953,593 A (KUHRTS) 11 October 2005 (11.1 lines 22-60; column 8, lines 36-45.		20-33, column 6,	1-41
Further documents are listed in the continuation of Box C.	See patent fa	mily snay	
Special categories of cited documents:			national filing date or priority
A" document defining the general state of the art which is not considered to be of particular relevance.	date and not in principle or the	conflict with the applica any underlying the inves-	ion but cited to understand the ion
entice application or patent published on or after the international filing date	· considered agve		sinsed invention causes be d to involve an inventive step
"document which may threw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	considered to in combined with	volve sa inventive step t 25e et mors eliter such d	powersta, such combination
"document referring to an oral disolosure, use, exhibition or other means document published prior to the international filing data but later than the priority data claimed		o a person skilled in the o per of the asme patent fa	
ate of the actual completion of the international search	Date of mailing of the i	nternational search	report
0 March-2008 (10,03,2008)	21 MAR 201	报	<u></u>
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P.O. Box 1450 Alexandria, Virginia 22313-1450 acsimile No. (571) 273-3201	Telephone No. (571)	72-0600	Bo
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from the	PAI	ENT COOPE	ERATION TRE	LATY
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JENNIFER M. MCCALLU				PCT
THE MCCALLUM LAW I	FIRM, LLC		i	
ERIE, CO 80516			li i i i i i i i i i i i i i i i i i i	RITTEN OPINION OF THE ONAL SEARCHING AUTHORITY
			INTERNATIO	ONAL SEARCHING AUTHORITI
				(PCT Rule 43bis.1)
			Date of mailing (day/month/year)	21 MAR 2008
Applicant's or agent's file r	eference		FOR FURTHER	ACTION
007184-15		•		See paragraph 2 below
International application No). Inter	national filing date	(day/month/year)	Priority date (day/month/year)
PCT/US04/11485	12 A	pril 2004 (12.04.20	004)	10 April 2003 (10.04.2003)
International Patent Classif				
IPC(8): A61K 9/14(2006 USPC: 424/489,499				
Applicant		1	•	
PR PHARAMACEUTICAI	LS			
1. This opinion contains i	ndications relating t	o the following iten	ns:	
Box No. I	Basis of the opini	on		
Box No. II	Priority	٠		•
Box No. III	Non-establishmer	at of opinion with re	egard to novelty, inve	ntive step and industrial applicability
Box No. IV	Lack of unity of i	nvention		·
Box No. V			s.1(a)(i) with regard to ons supporting such s	o novelty, inventive step or industrial tatement
Box No. VI	Certain document	s cited		
Box No. VII	Certain defects in	the international ap	plication	
Box No. VIII	Certain observation	ons on the internation	onal application	
2. FURTHER ACTIO				_
International Prelimina	ary Examining Aut	hority ("IPEA") e EA and the chosen	xcept that this does IPEA has notified the	be considered to be a written opinion of the not apply where the applicant chooses an he International Bureau under Rule 66.1bis(b) ered.
IPEA a written reply to	gether, where appr	opriate, with amend	iments, before the ex	PEA, the applicant is invited to submit to the piration of 3 months from the date of mailing whichever expires later.
For further options, see				
3. For further details, see	notes to Form PCT/	ISA/220.		
Name and mailing address		Date of comple	etion of this opinion	Authorized officer
Mail Stop PCT, Attr Commissioner for P		10 March 2008	3 (10.03.2008)	Konata M. George
P.O. Box 1450		10000		0 000
Alexandria, Virginia	22313-1450			Telephone No. (571) 272-0600

P.O. Box 1430
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201
Form PCT/ISA/237 (cover sheet) (April 2007)

nternational	application	No.
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PCT/US04/11485

Box N	lo. I Basis of this opinion
1. With	regard to the language, this opinion has been established on the basis of:
	the international application in the language in which it was filed
	a translation of the international application into, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2	This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
	regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been lished on the basis of:
a.	type of material
	a sequence listing
	table(s) related to the sequence listing
b.	format of material
	on paper
	in electronic form
c.	time of filing/furnishing
	contained in the international application as filed.
	filed together with the international application in electronic form.
	furnished subsequently to this Authority for the purposes of search.
4.	In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additi	ional comments:
	•

Form PCT/ISA/237 (Box No. V) (April 2007)

International application No. PCT/US04/11485

Statement		
Novelty (N)	Claims 1-41	Y
,	Claims NONE	No
Inventive step (IS)	Claims 1-41	Y
m. o.m. o o.ep (.e.)	Claims NONE	
Industrial applicability (IA)	Claims 1-41	YI
inducial approximation (113)		N
Citations and explanations:		
preparing microparticles comprising preparing (apprising a solvent (c) passing the first and secons reparticles followed by collecting the particles and a solvent. It is not taught, however, a separatus under laminar flow conditions. Claims 1-41 meet the criteria set out in P	d phases through a packed bed apparatus u Kuhrts discloses a technique involving or cond phase comprising a solvent only and	ander laminar flow conditions to form he phase comprising a polymer, an acti forming the particles by a packed bed
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PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 007184-15	FOR FURTHER ACTION	See item 4 below	
International application No. PCT/US2004/011485	International filing date (day/month/year) 12 April 2004 (12.04.2004)	Priority date (day/month/year) 10 April 2003 (10.04.2003)	
International Patent Classification (8th See relevant information in Form P	edition unless older edition indicated) CCT/ISA/237		
Applicant PR PHARMACEUTICALS			

1.	This international preliminary re International Searching Authori		r I) is issued by the International Bureau on behalf of the
2.	This REPORT consists of a total	l of 4 sheets, including this co	over sheet.
	In the attached sheets, any refer to the international preliminary		the International Searching Authority should be read as a reference er I) instead.
3.	This report contains indications	relating to the following item	s:
	Box No. I	Basis of the report	
	Box No. II	Priority	
	Box No. III	Non-establishment of opin applicability	aion with regard to novelty, inventive step and industrial
	Box No. IV	Lack of unity of invention	
	Box No. V		Article 35(2) with regard to novelty, inventive step or industrial explanations supporting such statement
	Box No. VI	Certain documents cited	
	Box No. VII	Certain defects in the inter	national application
	Box No. VIII	Certain observations on th	e international application
4.			gnated Offices in accordance with Rules 44 <i>bis</i> .3(c) and 93 <i>bis</i> .1 but er Article 23(2), before the expiration of 30 months from the priority
			Date of issuance of this report 24 February 2009 (24.02.2009)
	The International Bure	au of WIPO	Authorized officer
	34, chemin des Col 1211 Geneva 20, Sv		Nora Lindner
Facsin	nile No. +41 22 338 82 70		e-mail: pt11.pct@wipo.int
Form F	PCT/IB/373 (January 2004)		

From the INTERNATIONAL SEARCHING AUTHORITY	WI COOLERATION IN	eat i
To: JENNIFER M. MCCALLUM THE MCCALLUM LAW FIRM, LLC 132 KOLAR CT. ERIE, CO 80516	•	PCT RITTEN OPINION OF THE ONAL SEARCHING AUTHORITY
		(PCT Rule 43bis.1)
	Date of mailing (day/month/year)	2 1 MAR 2008
Applicant's or agent's file reference	FOR FURTHER	ACTION See paragraph 2 below
	tional filing date (day/month/year)	Priority date (day/month/year)
· · · · · · · · · · · · · · · · · · ·	il 2004 (12.04.2004)	10 April 2003 (10.04.2003)
International Patent Classification (IPC) or both na		10.14.11.2002 (1010.112002)
IPC(8): A61K 9/14(2006.01),9/50(2006.01) USPC: 424/489,499 Applicant PR PHARAMACEUTICALS		
This opinion contains indications relating to the state of the st	ne following items:	
Box No. I Basis of the opinion		
Box No. II Priority	•	
Box No. III Non-establishment o	f opinion with regard to novelty, inve	entive step and industrial applicability
Box No. IV Lack of unity of inve	ention	
	under Rule 43bis.1(a)(i) with regard to sand explanations supporting such s	o novelty, inventive step or industrial tatement
Box No. VI Certain documents ci	ited	
Box No. VII Certain defects in the	international application	
Box No. VIII Certain observations	on the international application	
2. FURTHER ACTION		
If a demand for international preliminary extended international Preliminary Examining Author	rity ("IPEA") except that this does and the chosen IPEA has notified the	be considered to be a written opinion of the not apply where the applicant chooses an he International Bureau under Rule 66.1bis(b) ered.
IPEA a written reply together, where appropr of Form PCT/ISA/220 or before the expiration	iate, with amendments, before the ex	PEA, the applicant is invited to submit to the piration of 3 months from the date of mailing whichever expires later.
For further options, see Form PCT/ISA/220.		·
3. For further details, see notes to Form PCT/ISA	بر/220. مسيد	
Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer/
Mail Stop PCT, Attn: ISA/US Commissioner for Patents	10 March 2008 (10.03.2008)	Konata M. George
P.O. Box 1450 Alexandria, Virginia 22313-1450	· ·	Telephone No. (571) 272-0600

Facsimile No. (571) 273-3201
Form PCT/ISA/237 (cover sheet) (April 2007)

International application No.
PCT/US04/11485

Box No. I Basis of this opinion	
	_
1. With regard to the language, this opinion has been established on the basis of:	
the international application in the language in which it was filed	
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 This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to thi Authority under Rule 91 (Rule 43bis.1(a)) 	s
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of:	
a. type of material	
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contained in the international application as filed.	
filed together with the international application in electronic form.	
furnished subsequently to this Authority for the purposes of search.	
4. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.	
5. Additional comments:	
·	

International application No. PCT/US04/11485

Statement			
Novelty (N)	Claims	1-41	YI
violet, (c.,		NONE	
Laurantina atau (IC)	Claima	1.41	Yi
Inventive step (IS)		1-41 NONE	
Industrial applicability (IA)	Claims		
	Claims	NONE	N
Citations and explanations:			
Claims 1-41 meet the criteria set out in Po	T Article 33(2)	(3) hecause the prior art does not te	ach or fairly suggest a metho
preparing microparticles comprising preparing (a) first phase con	aprising a solvent, an active agent and	i a polymer, (b) a second ph
mprising a solvent (c) passing the first and second croparticles followed by collecting the particles.	d phases through	a packed bed apparatus under lamin	ar flow conditions to form
ent and a solvent. It is not taught, however, a sec	ond phase comp	rising a solvent only and forming the	particles by a packed bed
paratus under laminar flow conditions.			
Claims 1-41 meet the criteria set out in Poimed can be made or used in industry.	CT Article 33(4)	, and thus have industrial applicabilit	y because the subject matte
mico can be made or assa in measury.		•	
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